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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/303,315      | 04/30/99    | PEARLMAN             | 103604/005          |

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HM22/0313

| EXAMINER |
|----------|
| ZEMAN, M |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631     |              |

DATE MAILED: 03/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Office Action Summary**

Application No.

09/303,315

Applicant(s)

PEARLMAN, HUGENE S.

Examiner

Mary Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 January 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 5-11, 13-17, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 12, 18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)                      18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2                      20) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

Applicant's election of the hepatitis algorithm as the specific species to be examined in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Generic claims 1-4 and 21-24 as well as species claims 12 and 18 are under examination.

Claims 5-11, 13-17, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 7.

### *Information Disclosure Statement*

The IDS, filed 9/13/99, has been considered. An initialed copy of the PTO-1449 is enclosed with this action.

### *Drawings*

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect can be deferred until the application is allowed by the examiner.

### *Specification*

The disclosure is objected to because of the following informalities: Page 60 contains a figure and/or diagram in the text which is not permitted. This figure and/or diagram should be canceled from the text, and resubmitted as a Figure, as necessary. If an additional Figure is submitted, the specification should then be amended to describe the Figure in the appropriate section.

Appropriate correction is required.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps that constitute "the hepatitis algorithm" or the "hepatitis B algorithm" are missing from the claims. As each algorithm is different depending on the disease to be diagnosed, the steps are necessarily different. The claims should recite what clinical tests are to be performed, in what order, and under what conditions for each disease.

Claims 12, 18 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 12 and 18 recite the limitation "the XXX algorithm" in reference to claim 1. There is insufficient antecedent basis for this limitation in the claims. Claim 1 does not set forth either "a hepatitis algorithm" or "a hepatitis B algorithm" such that the terms "**the** hepatitis algorithm" or "**the** hepatitis B algorithm" have proper antecedent basis.

Claim 21 is vague and indefinite in the recitation that the apparatus comprises "clinical tests". How can an apparatus comprise a test? An apparatus or computer can comprise information about the tests, directions for executing the tests, words or data describing the test, or means for performing a test, but cannot comprise the test itself. Limitation c of claim 21 is confusing, and does not clearly define a feature of the apparatus being claimed.

Claim 22 is unclear as to its significance- how does the limitation that the tests are equal in data size further limit the apparatus?

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4 and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Armstrong et al. (US 6,099,469).

Claims 1-4 are drawn to a computer assisted method for performing a series of clinical tests that are diagnostic for various disease states. Claims 1-4 are generic, and do not specify any particular disease state. Claims 21-24 are drawn to an apparatus or system for performing the same method.

Armstrong et al. (US 6,099,469) disclose a disease specific algorithm for use in a computer assisted method, which analyzes what clinical tests should be performed. The particular disease state of Armstrong et al. is acute myocardial infarction. A first test is performed on the sample, then, based upon the result of that test in comparison with preset guidelines, a second test is run. This process is repeated until an endpoint is reached. That endpoint is a diagnosis of a condition (columns 4-11 specifically describe the tests, etc.). Figures 1B-1F set forth the decision tree of clinical tests and diagnoses used in the particular algorithm for the disease state. Figure 2, and the discussion from column 11 line 30 to column 14, line 25, set forth various systems and apparatus for performing the method. Therefore, the disclosure of Armstrong et al. meet the limitations of the above rejected claims.

Claims 1-4 and 21-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Carlson et al. (US 6,140,065).

Generic claims 1-4 and 21-24 are described above.

Carlson et al. (US 6,140,065) disclose computer assisted methods for diagnosing a disease state based upon a reflex algorithm. The particular disease state of Carlson et al. is prostate disease. The particular algorithm of Carlson et al. differentially diagnoses between benign prostate diseases and prostate adenocarcinomas. Columns 2-4 discuss the particulars of the diagnostic algorithm, and the claims set forth a detailed diagnostic algorithm to be used. The

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paragraph bridging columns 3 and 4 set forth a system or apparatus for performing the algorithm. Therefore, Carlson et al. meet the limitations of the above rejected claims.

Claims 1-4, 12, 18 and 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Sreevatsan et al. (1998).

Claims 12 and 18 set forth that the algorithm is a "hepatitis algorithm" but put forth no specific tests or conditions.

Sreevatsan et al. (Journal of Clinical Microbiology 1998 Vol 36 No.7 pages 1895-1901. PTO-1449) disclose reflex algorithms for the differential diagnoses of Hepatitis C Virus serotypes. HCV infection is one cause of hepatitis seen in patients. Figure 3 of Sreevatsan et al. sets forth the decision tree to be used in the process. These computer assisted reflex algorithms were able to accurately diagnose HCV serotype, as checked by direct sequencing of clinical samples. Therefore, Sreevatsan et al. meet the limitations of the above rejected claims.

### *Conclusion*

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133. The examiner can be reached between the hours of 7:30 am and 5:00 pm Monday through Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

The fax number for this Art Unit is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose telephone number is (703) 305-3524.

mkz  
March 6, 2001

  
MARY K. ZEMAN  
PATENT EXAMINER  
FU 1631